

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Akira NAKAGAWARA et al.

New 371 Patent Application

Filed: Herewith, June 9, 2006

Attorney Docket No.: 7388/88180

Confirmation No. Not Yet Assigned

Customer No.: 42798

For: METHOD OF DETERMINING CLINICAL SEVERITY OF FALS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO/SB/08 are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form PTO/SB/08, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form PTO/SB/08 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- (X) **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.
- () **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- () the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or*
- () the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- () **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- () **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

- (X) Copies of the references listed on the enclosed Form SB/08 are enclosed herewith. Copies of any U.S. Patents and any U.S. Patent Application Publications are not enclosed.
- () A copy of the International Search Report is enclosed herewith.
- () A copy of the Supplementary European Search Report is enclosed herewith.

- () The references listed on the enclosed Form PTO/SB/08 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (<i>check one</i>)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under 37 CFR 1.97(e)

- () The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- () The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

- () The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

- (X) No fee is owed by the applicant(s).
- () The IDS Fee of \$180 under 37 CFR 1.17(p) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$180.00.
☐ Charge Deposit Account No. 06-1135, under Order No. , in the amount of \$0.00.
(A duplicate copy of this communication is enclosed for that purpose.)

Authorization to Charge Additional Fees

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 06-1135. (A duplicate copy of this communication is enclosed for that purpose.)

Instructions as to Overpayment

- ☒ Credit Account No. 06-1135.
☐ Refund

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY



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Michael A. Sanzo, Reg. No. 36,912

Date: June 9, 2006

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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.

³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

IAP12 Rec'd PCT/PTO JUN 2006

PTO/SB/08a Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number		371 Patent Application	
				Filing Date		Herewith, June 9, 2006	
				First Named Inventor		Akira NAKAGAWARA	
				Art Unit		Not Yet Assigned	
				Examiner Name		Not Yet Assigned	
Sheet	2	of	2	Attorney Docket		7388/88180	
NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ²
		Catherine KUNST et al., "Mutations of SOD1 associated with amyotrophic lateral sclerosis cause novel protein interactions," Nature Genetics, Vol. 15, No. 1, pp. 91-94 (Jan 1997)					
		Jun-ichi NIWA et al., "Dorfin ubiquitylates mutant SOD1 and prevents mutant SOD1-mediated neurotoxicity," The Journal of Biological Chemistry, Vol. 277, No. 39, pp. 36793-36798 (1997)					
Examiner Signature					Date Considered		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.